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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/954,494	09/17/2001	James G. Castillo	3863.015	8042

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06/05/2002

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EXAMINER

KIM, VICKIE Y

ART UNIT

PAPER NUMBER

1614

DATE MAILED: 06/05/2002

5

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/954,494

Applicant(s)

CASTILLO, JAMES G.

Examiner

Vickie Kim

Art Unit

1614

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-14 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-14 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s) ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

Response to Arguments

1. Applicant's arguments filed March 23, 2002 have been fully considered but they are not persuasive. Detailed response is followed after the summary of previous office action.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 1-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sipos(US 5,993,836) in view of Castillo(US 5,993,836).

The claims read on a method of applying local anesthetics in lipophilic base in lower alcohols to provide local anesthesia.

Sipos teaches a topical anesthetic composition and a method of obtaining an enhancement of its anesthetic activity by combining the anesthetic agent(e.g. lidocaine, prilocaine, or mixture thereof) with an effective amount of a penetrant accelerator(i.e. cyclohexyl substituted alkanols) in vehicles including lower alcohols (e.g. ethanol , iso-propanol); see abstract and claims 1-25, especially column 9, lines 26-27 and examples 7-11. Sipos teaches C5-17 aliphatic alcohols as the said potentiator(e.g. phenyl alcohols); see columns 4-5. For instance, example 9 at column 15, teaches a topical

Art Unit: 1614

anesthetic gel composition comprising 50% ethanol, 4% anesthetic agent, and 12% penetrant accelerator(i.e.cyclohexyl alkanols), 5% carbosil, and so on.

Applicant's claims differ because they use and include specific terms "lipophilic base", "homogeneous solution", "volatile solvent", "cool sensation", "evaporation", etc.

However it would have been obvious to one of ordinary skill in the art to modify Sipos into claimed composition because the deficiencies in Sipos are commonly known to any artisan having ordinary skill in the art wherein they are equivalently substitutable due to inherent features, well known techniques, common knowledge, etc.

In any events, Castillo supports this examiner's allegation by teaching about a topical local anesthetic treatment comprising the steps of incorporating eutectic mixture of lidocaine and prilocaine within a lipophilic base(C 8-18 aliphatic alcohols) to provide rapid-onset, stability and optimal absorption; see abstract and claim 10. It further teaches suitable additives such as thickeners, thinner, stabilizers, surfactants, etc.

Thus One would have been motivated to make the local anesthetic containing composition comprising lidocaine or eutectic mixture of lidocaine+prilocaine, incorporated within lipophilic base, mix into volatile solvent(i.e. ethanol, isopropanol) to maximize therapeutic efficacy with optimal dosage, delivery including penetration as evidenced by Sipos; see test comparison with various vehicles; see table V at column 16-17.

All the minor variations required in dependent claims are properly included in this rejection because the minor variations including the selection of optimal dosages, routes of administration, or variable applications in order to determine the most effective

Art Unit: 1614

treatment is well within the skilled level of artisan having ordinary skill in the art, and is obvious.

One would have been motivated to combine these references and make the modification because they are drawn to same technical fields (constituted with same (or similar) ingredients and share common utilities, and pertinent to the problem which applicant is concerning. MPEP 2141.01(a).

.....
In response to applicant's argument that Sipo's teaching fails to teach the penetration enhancement with evaporating volatile solvent due to the fact that Sipo's composition must use with Band-Aid which prevents evaporation of volatile solvents.

This examiner points out that Sipo's teaching is about not only application with Band-Aid but also without Band-Aid, see column 16, example 12. Sipo teaches clearly the deep penetration through intact skin **without any additional accelerator** would be achieved. Evaporation of volatile solvents(e.g. ethanol or propanolol) is inherited feature where one would expect the evaporation and the claims are met. Applicant's argument is based on narrow interpretation of examples whereas the patented invention should be read into all the topical applications and formulations including solutions, creams, gels, aerosols and the like, see column 6, lines 50-65. Therefore, Sipo's teaching is valid and Sipo's teaching would include all the critical elements inherently wherein cool sensation is sensed when volatile solvent(e.g. ethanol) is evaporating and pharmaceutical composition should be a homogeneous solution medium or long chain blanching alcohol could be lipophilic), if not, one would expect the reasonable success of the modification of Sipo's in view of Castillo wherein one would have been motivated

Art Unit: 1614

to make the modification to maximize the therapeutic efficacy where the pharmaceutical and dermatological acceptability or stability is enhanced by such modification.

The newly amended claims 4-5 are properly included in this rejection because ethanol is alcohol and denatured ethanol also included in the term ethanol absent evidence to the contrary.

Conclusion

2. All the pending claims are rejected. No claims are allowed.
3. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vickie Kim whose telephone number is 703-305-1675. The examiner can normally be reached on Tuesday-Friday.

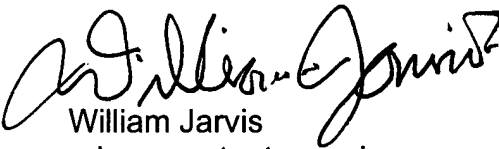
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne Seidel can be reached on 703-308-4725. The fax phone numbers for the organization where this application or proceeding is assigned are 703-

Art Unit: 1614

746-3165 for regular communications and 703-746-3165 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

Vickie Kim,
Patent examiner
May 30, 2002
Art unit 1614


William Jarvis
primary patent examiner